

ORIGINAL

authorized to combine, mix, or alter ingredients of a drug to create a medication tailored to the needs of an individual patient ("compounding pharmacy").

4. A compounded medication generally is prescribed only after a licensed medical professional considered the particular patient's diagnoses, medical condition, individual health factors, and reactions to other medications and determined that commercially available medications are not as beneficial or may be inappropriate or harmful to a particular patient. The ingredients of each compounded medication then are combined by the pharmacist in the exact strength and dosage required for the particular patient's unique circumstances. For example, if a patient is allergic to a specific ingredient (such as a dye or preservative) in an off-the-shelf medication approved by the Food and Drug Administration ("FDA") (an "FDA-Approved Medication") a compounded medication could be prepared by a compounding pharmacy excluding the substance that triggered the allergic reaction. A compounded medication also could be prescribed when a patient cannot consume a medication by traditional means, such as an elderly patient or child who cannot swallow an FDA-approved pill and needed the drug in a liquid form that was not otherwise available.

5. Given that compounded medications are custom-made for particular patients, typically they are much more expensive than mass-produced prescription medications. Further, because compounded medications are custom made to fit the unique needs of each patient, the FDA does not regulate or approve compounded medications. Therefore, the FDA also does not verify the safety or effectiveness of compounded drugs. Due to the unique and individualized nature of compounded medications, such medications are neither commercially available nor distributed in mass quantities.

COUNT 1

(Conspiracy to Commit Healthcare Fraud, 18 U.S.C. § 1349)

The Grand Jury charges:

6. The factual allegations of paragraphs 1 through 5 of this indictment are incorporated by reference as if fully rewritten herein.

7. From in or around March 2014 to in or around April 2016, in the Northern District of Ohio, Western Division, and elsewhere, Defendant KEVIN CLAY did knowingly and intentionally combine, conspire, confederate, and agree with M.M., S.H., L.P., and others known and unknown to the Grand Jury, to commit offenses under Title 18, United States Code, Chapter 63, to wit:

a. knowingly and willfully executed, and attempted to execute, a scheme and artifice to defraud health care benefit programs, and to obtain by means of false and fraudulent pretenses, representations, promises, and omissions, money, and property owned by, and under the custody and control of the health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347.

Object of the Conspiracy

8. It was a goal of the conspiracy for KEVIN CLAY, M.M., S.H., L.P., and others, to unlawfully enrich themselves by causing healthcare insurance companies to issue reimbursements for expensive medically unnecessary compounded medications, collecting a percentage of those reimbursements and failing to disclose to the insurance companies that “patients” were being paid for their own prescriptions.

Manner and Means of the Conspiracy

9. CLAY and M.M. arranged a meeting with the owner of Pharmacy #1, a compounding pharmacy in Cleveland, Ohio. The owner agreed to fill prescriptions, manufacture the creams and gels, and bill the individual insurance company. The owner would take approximately 70% of the insurance money and provide the rest of the money to CLAY and M.M. for each prescription. The owner knew CLAY and M.M. planned to pay individual “sales representatives” a commission for prescriptions those individuals received as patients. Pharmacy #1 provided CLAY and M.M. prescription pads for compounding creams intended to be disseminated to its patients. The type of compounding prescriptions marketed by Theramedical ranged in cost to the insurance company from several hundred dollars to over ten thousand dollars per prescription.

10. Prior to involving more people, M.M. did a “test run” to see how the process worked. He approached S.H. who operated a medical practice in Perrysburg, Ohio. He gave S.H. Pharmacy #1’s prescription paper and told her he needed a pain cream. S.H. wrote the prescription. Pharmacy #1 fulfilled the prescription and within weeks paid M.M. for his own prescription. CLAY did his own “test run” with a different doctor using Pharmacy #1 that was successful.

11. The owner of Pharmacy #1 told M.M. that the insurance carriers used by Fiat Chrysler Automotive (FCA) employees covered these type of compounding prescriptions and FCA employees would be good targets for them. FCA employees had insurance coverage through the health care benefit programs Medical Mutual of Ohio and Blue Cross Blue Shield.

12. M.M.’s relative, L.P., worked for FCA at Jeep in Toledo, Ohio. M.M. approached L.P. and asked her to recruit other Jeep employees to obtain compounding

prescriptions. L.P. agreed. CLAY and M.M. named these co-conspirators as “marketers” or “sales representatives” of Theramedical LLC.

13. “Marketers” or “sales representatives” participated in the scheme to defraud by recruiting individual beneficiaries who were willing to obtain compounded medications. At times, the “marketers” or “sales representatives” used pre-formulated prescription forms prior to being evaluated by a doctor and disseminated these pre-formulated prescription forms to other “patients” before the doctor visit. That form was then submitted to S.H. for approval based on the recruited beneficiaries' request for a compounded medication.

14. Once the prescription was filled by the pharmacy, CLAY and M.M. provided a kickback to the “patient” and the “marketer(s)” who recruited the “patients” in the form of an IRS Form 1099 from Theramedical LLC. The ultimate goal was to generate as many prescriptions for pre-formulated, expensive and medically unnecessary compounded medications, rather than prescribe an FDA-approved medication or a medication tailored made to the unique needs of the patient.

15. After CLAY and M.M. had this structure in place, S.H.’s patients and prescriptions increased substantially. In 2014, S.H. prescribed at least \$7.37 million worth of compounding creams. In 2015, S.H. prescribed at least \$3.19 million worth of compounding creams. Of these compounding creams, approximately \$3.74 million were for Jeep employees who received payment for their personal prescriptions.

16. The scheme and artifice to defraud, and to obtain money and property, included false and fraudulent pretenses, representations, promises and omissions because neither CLAY, M.M., S.H., Pharmacy #1 nor the “patients” informed the insurance companies that patients were

being paid for their individual prescriptions and that in many instances they were medically unnecessary.

17. CLAY and M.M. made similar agreements with other compounding pharmacies to increase their geographic area they could serve. Eventually, Medical Mutual of Ohio and Blue Cross Blue Shield refused to cover this type of compounding creams.

18. When this occurred, CLAY and M.M. used the same co-conspirators including S.H. and L.P., to get a “wellness” supplement. The payment scheme was the same for this supplement.

19. CLAY and M.M. split the profits equally.

Acts in Furtherance of the Conspiracy

20. In furtherance of the conspiracy and to affect the objects of thereof, Defendant and others known and unknown to the Grand Jury committed the following acts, among others, in the Northern District of Ohio, and elsewhere:

21. On or about the dates listed below, for the purpose of executing and attempting to execute the foregoing scheme and artifice to defraud, Pharmacy #1 in Cleveland, Ohio used its Huntington Bank account ending in 1831 to transmit and cause to be transmitted, writings, signs, signals, pictures and sounds by means of wire communications, in interstate commerce, to wit: wire transfers to Theramedical, LLC’s PNC bank account ending in 9582 routed through Virginia, as set forth in the table below:

<b>Approx. Date</b>	<b>Approx. Amount (USD)</b>
9/24/2014	\$354,836.00
11/17/2014	\$390,000.00
11/25/2014	\$270,274.00

12/17/2014	\$400,000.00
12/18/2014	\$400,000.00
12/30/2014	\$200,000.00
1/22/2015	\$358,977.00
3/2/2015	\$1,146,470.00

22. On or about the dates listed below, for the purpose of executing and attempting to execute the foregoing scheme and artifice to defraud, Theramedical LLC used its PNC bank account ending in 9582 to transmit and cause to be transmitted, writings, signs, signals, pictures and sounds by means of wire communications, in interstate commerce, to wit: wire transfers to Data Service Center in Toledo, Ohio, as set forth in the table below:

<b>Approx. Date</b>	<b>Approx. Amount (USD)</b>
11/25/2014	\$264,864.46
12/23/2014	\$410,711.55
1/29/2015	\$281,683.84
3/2/2015	\$83,289.25
3/3/2015	\$406,941.09
5/14/2015	\$131,836.20
6/2/2015	\$139,142.86
7/10/2015	\$48,758.59

All in violation of Title 18, United States Code, Section 1349.

COUNT 2

(Health Care Fraud, 18 U.S.C. §§ 1347 and 2)

The Grand Jury further charges:

23. The factual allegations of paragraphs 1 through 5 and paragraphs 8 through 22 of this indictment are incorporated by reference herein

24. In or around March 2014 to in or around April 2016, in the Northern District of Ohio, Western Division, and elsewhere, Defendant KEVIN CLAY, M.M., S.H., L.P., and others did knowingly and willfully execute and attempt to execute the above-described scheme and artifice to defraud a health care benefit program, that is medical payment for compounded drugs from Fiat Chrysler Automotive's Medical Mutual of Ohio and Blue Cross Blue Shield, and to obtain by means of materially false and fraudulent pretenses, representations, promises, and omissions, money owned by and under the custody and control of said insurance company, in connection with the delivery of a payment for health care benefits, items or services.

All in violation of Title 18, United States Code, Sections 1347 and 2.

COUNT 3

(False Statement, 26 U.S.C. § 7206(1))

The Grand Jury further charges:

25. On or about September 15, 2015, in the Northern District of Ohio, Defendant KEVIN CLAY, did willfully make and subscribe a U.S. Individual Income Tax Return (Form 1040) for the 2014 tax year, which was verified by a written declaration that it was made under the penalties of perjury and which he did not believe to be true and correct as to every material matter. This U.S. Individual Income Tax Return (Form 1040), which was prepared and signed in the Northern District of Ohio, Western Division, and was filed with the Internal Revenue Service, stated on line 43 that CLAY had taxable income of \$582,408, whereas CLAY then and



there well knew he had taxable income substantially in excess of \$582,408, in violation of Title 26, United States Code, Section 7206(1).

COUNT 4

(False Statement, 26 U.S.C. § 7206(1))

The Grand Jury further charges:

26. On or about May 7, 2015, in the Northern District of Ohio, Defendant KEVIN CLAY, did willfully make and subscribe an Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code (Form 1023), which was verified by a written declaration that it was made under the penalties of perjury and which he did not believe to be true and correct as to every material matter. That Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code (Form 1023), which was prepared and signed in the Northern District of Ohio, Western Division, and was filed with the Internal Revenue Service, stated on Page 10, Part X, Line 1a that the Clay Foundation was not a private foundation, whereas CLAY then and there well knew the Clay Foundation was a private foundation and did not qualify for public charity status in violation of Title 26, United States Code, Section 7206(1).

FOFEITURE

The Grand Jury further charges:

27. For the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C), Title 18, United States Code, Section 982(a)(7), and Title 28, United States Code, Section 2461(c), the allegations of Count 1 and 2 are incorporated herein by reference. As a result of the foregoing offenses, Defendant KEVIN CLAY, shall forfeit to the United States, any property, real or personal, which constitutes or is derived from proceeds traceable to the violations charged in Count 1; and any property, which constitutes or is derived, directly or

indirectly, from gross proceeds traceable to the commission of the violations charged in Counts 2 and 3; including, but not limited to, the following:

- a. 2014 White Land Rover Sport Range Rover, VIN: SALWR2TF4EA503522, titled to Kevin Clay;
- b. \$14,719.56 seized from PNC Bank account #41-0891-2755 in the name of Theramedical Laboratories LLC;
- c. \$399,225.07 seized from PNC Bank account #41-0891-3002 in the name of The Clay Foundation LLC;
- d. \$5,355.09 seized from PNC Bank account #42-7311-9603 in the name of Theramedical LLC;
- e. \$17,279.92 seized from PNC Bank account #42-7311-9582 in the name of Theramedical LLC;
- f. \$101,342.06 seized from PNC Bank account #4221201672 in the name of Kevin A. Clay and Matthew S. M.M.;
- g. \$29,000.00 in U.S. Currency seized from Kevin Clay on June 7, 2016;
- h. Miscellaneous Jewelry seized from Kevin Clay on June 7, 2016;
- i. Miscellaneous Gold and Silver bars and coins seized from Kevin Clay on June 7, 2016;
- j. \$1,850.68 Seized from PNC Bank Account #41-1519-3146 in the Name of KCMM Management LLC; and,
- k. Real Property located at 29640 Shelbourne Road, Perrysburg, Ohio Permanent Parcel Number P60-300-701401037000, titled to 29640 Shelbourne Road LLC.

A TRUE BILL.

Original document - Signatures on file with the Clerk of Courts, pursuant to the E-Government Act of 2002.